THIS IS A SOURCES SOUGHT NOTICE to determine the availability and capability of small businesses (including certified 8(a), Small Disadvantaged, and HUBZone firms; veteran and service-disabled veteran-owned small businesses, and women-owned small businesses. This notice is for planning purposes only, and does not constitute an Invitation for Bids, a Request for Proposals, Solicitation, Request for Quotes, or an indication the Government will contract for the items contained herein. This notice is not to be construed as a commitment on the part of the Government to award a contract, nor does the Government intend to pay for any information submitted as a result of this notice. The Government does not reimburse respondents for any cost associated with submission of the information being requested or reimburse expenses incurred to interested parties for responses to this sources sought. Any responses received will not be used as a proposal.

The Food and Drug Administration's (FDA), Center for Drug Evaluation and Research (CDER) in Maryland is seeking to identify any sources with capabilities or prior experience that can provide access support services to Over-the-Counter (OTC) Drug Utilization Data in accordance with the following draft statement of work or specifications. This is a potential hybrid purchase order to include both firm-fixed price and labor hours, for a (1) one-year Base Period and (2) two, one-year Option Periods.

OBJECTIVE:

The Contractor shall provide FDA personnel with *real-time, immediate, direct, multi-user, desktop* access to a *currently existing, commercially available* data resource through an existing and user-friendly interface tool for Over-the-Counter (OTC) drug utilization data that include household and/or patient/intended user *demographics*, drug treatment patterns, and indications or ailments intended for treatment in the *outpatient* setting using surveys and/or other appropriate methodologies. This data resource shall have the capability of providing national patterns of OTC drug utilization patterns in the *outpatient* setting through the use of *projection or other appropriate methodologies* that are scientifically sound and transparent to FDA personnel.

STATMENT OF WORK or SPECIFICATIONS:

The Contractor shall provide the necessary personnel, materials, services, facilities, and otherwise do all things necessary for or incident to the performance of the work as described below:

A. Data Requirements for Over-the-Counter (OTC) Drug Utilization Data: *Unlimited* Access to OTC Drug Utilization Data

a. The Contractor shall provide continuous automated access to *de-identified HIPAA-compliant* data resources on OTC drug product usage including, but not limited to household and/or patient/intended user *demographics*, drug treatment patterns, and indications or ailments intended for treatment in the *outpatient* setting. The source data can be obtained from a survey of household purchasing patterns or other electronic data sources. FDA requires access to such data to obtain national patterns of OTC drug product utilization. The data resource(s) shall have the capability of providing both current and historical national-level OTC drug product utilization. The data shall have a maximum of a 6-month lag time between the date of OTC drug product purchase and date of data availability for FDA use.

b. The OTC drug utilization data shall include the number of households and/or patient/intended users, and household panel members and/or patient/intended users in the sample; characterization of households and/or patient/intended users in the sample in terms of number of individuals in the household, income level, and U.S. Census Region. The Contractor shall provide a comparison to national figures.

c. The household and/or patient/intended user *demographic* data shall include the number and percent of patient populations of special interest to the FDA, including infants (<2 years), children (≤ 17 years), women of childbearing age (12-45 years), adults (18-64 years), and elderly (≥ 65 years), the number and percent of patients missing age as well as the *demographic* distribution of patients (age and sex required and additional characteristics such as race and U.S. Census Region).

d. The patient-specific basic data elements in the household shall include (but are not limited to): patient *demographics* of the patient/intended user such as age (specify method by which age is obtained and how it is displayed in canned reports, i.e.,. standard age groups, customized age groups, single years), gender, and specify if other data elements are available, such as race/ethnicity; income level; occupation; height and weight; clinical measures such as blood pressure, cholesterol, smoking status; alcohol use; availability of health insurance; and U.S. Census Regions.

e. The OTC drug-specific basic data elements shall include brand and generic drug products, including store name brand drug products; drug active ingredients; unit price code (UPC) and/or national drug code (NDC) number; strength of active ingredients; dosage form; size of drug product by milliliter (mL), number of tablets/capsules, and/or total doses available; manufacturer and/or re-packager; date of purchase; indication(s) for use or ailment(s) intended to treat or an acceptable surrogate such as therapeutic sub-categories, and source of drug (recommendation by healthcare

professional, self-purchase, sample provided). The Contractor shall provide the percentage of missing or incomplete data or information for each of these OTC drug-specific basic data elements. Of note, specific store names for store name brand products are not required but data on store name brand products, such as drug active ingredients, shall be included for analysis by the elements listed above.

f. The treatment-specific basic data elements shall describe the patient's ailment treatment category; concomitant use with other prescription or OTC drug products; duration of use; diagnosis code such as ICD-9/ICD-10 and date of diagnosis; and the patient demographics of the patient/intended user.

g. The data resource shall include a coding system that consists of drug and ailment coding levels for FDA data analyses; and if available, quantify the amount, frequency, and duration of OTC drug products used as well as the ailment intended to treat in the *outpatient* setting and the percentage of missing or incomplete information for each data element. For examining data on treatment of specified ailment or medical conditions, the data resource shall capture the OTC drugs purchased as well as other drugs used for the treatment of the ailment.

h. The existing user interface tool of the data resource(s) shall provide FDA staff the ability to select OTC drugs and market categories, and perform data reports at the active ingredient level, generic and brand products (including store name brand products), and any other data elements that may become available. The user interface tool(s) shall provide FDA staff the ability to perform data reports without or with minimal intervention by the Contractor and download in near *real-time*.

i. The Contractor shall *de-identify* the data for FDA use, and the methods used to *de-identify* the data shall be described and shall be *HIPAA-compliant*.

B. Data Requirements for Over-the-Counter (OTC) Drug Utilization Data: Projection or Other Appropriate Methodology

a. The Contractor shall project the data to the national level using a FDA approved *projection or other appropriate methodology*, which shall be *valid*, *reliable*, and *robust* with regard to OTC drug product purchase and use specifically, and the methods fully disclosed. Results from projections shall be comparable to estimates obtained from national benchmarks such as the U.S. National Census Data. The data resource(s) shall have *raw*/sample and projected numbers. The Contractor shall provide the frequency with which data are updated and methods for updates.

b. The Contractor shall provide *full disclosure of data collection, construction, coding, and configuration* to allow FDA staff to appropriately interpret findings and understand the construction and application of the *projection or other appropriate methodology*.

C. Complete Data Dictionary for Over-the-Counter (OTC) Drug Utilization Data Resource

The Contractor shall provide a current and complete *data dictionary*, including updates, and a description of their data resource(s), type of data, the data collection methodology, and the data elements demonstrating that the data resource(s) can evaluate OTC drug utilization data at the national level.

D. Technical Requirements and Capabilities of the Data Resources

a. The Contractor shall provide OTC drug utilization data that is *currently existing and commercially available*. Access to the data shall be *immediate, unlimited, direct*, via *desktop* and in *real-time. Direct* access shall include all upgrades, enhancements, and modifications to software and data.

Direct access shall be through an existing interface. This interface shall be user-friendly, transparent, and flexible to meet the FDA's needs and provide FDA staff the ability to select drugs and perform data reports by active ingredient, generic and brand products (including store name brand), and any other data elements that may become available, and download in near *real-time* manner and without or with minimal intervention by the Contractor. Minimally, the interface shall provide both predefined (e.g., canned) and custom reports. *Direct* access to the data resource(s) shall include the ability to download (or obtain in near *real-time* manner using other means) and analyze patient level data (as soon as available). FDA's preference is that unrestricted *direct* access to datasets shall be available on demand and without intervention by the Contractor.

b. The FDA shall purchase one site license for 20 certified users with option for up to 10 additional users. Individuals within the Office of Surveillance and Epidemiology as well as other authorized users within the FDA will need to access these data for their work.

c. The Contractor shall provide the FDA the ability to directly download or export data in SAS, MS Excel, or MS Access, in addition to ASCII format, from the Contractor's interface to FDA's external storage device and/or directly to the FDA server.

d. The Contractor shall provide access to the data resource(s) via a *secure* Internet or network-based method permitting simultaneous, multi-user access through a user friendly data query tool(s). Access to the data resource(s) shall be through a wide area network with transmission control protocol/Internet protocol (TCP/IP) running on a 10/1000 Mbs network. The network-based methods shall not necessitate any additions to the FDA communications infrastructure. FDA shall not support modem-based or dial-up access. Additionally, FDA shall not support or maintain Contractor's equipment or personnel on premises. The FDA standard browser package is Microsoft Internet Explorer Version 11.x and Firefox 24.x.

e. The Contractor shall specify any additional software and/or hardware (name and version) necessary to access the data. Any software installed on FDA computers for the purposes of accessing the data shall not use key-logging and/or network capturing functionality to transmit any data from the FDA system except for login information specific to the data and data (eg. SQL queries or similar methods) accessing the Contractor's application data sets.

f. The Contractor shall participate in the CDER *secure* electronic mail system (See Appendix G) to protect any sensitive data which may be transmitted electronically between the data vendor and the FDA. The FDA utilizes the virtual private network (VPN) to establish a trusted, encrypted TCP/IP tunnel for accessing data from a remote location. The virtual private network shall be a *firewall-to-firewall* encrypted tunnel utilizing *commercially available* software and industry standard IPSEC protocols. The Contractor shall conform to Section 508 standards. (See Appendix C)

E. Data Requirements for OTC Drug Utilization Data: Ad Hoc Data Analyses

The Contractor shall provide additional ad hoc data analyses or custom queries or product customization not available through the data tools not to exceed $TBD per year.

F. Onsite Training Programs and Training Materials

The Contractor shall provide training for users of the data, as well as training for FDA personnel who will support use of the data (e.g., technical users). The Contractor shall provide a minimum of two onsite training sessions per year.

The training sessions shall include an instructor led overview of the OTC data resource to the FDA staff with the ability to project via web-based presentation. A hands-on computer-based training for a maximum of 18 FDA staff members shall be provided on the use of the data and interface tool(s). The hands-on sessions shall include exercises with data queries with FDA content. The Contractor shall work with FDA COR to develop exercises with data queries relevant to FDA work.

The Contractor shall provide options for additional "on-demand" sessions either in person or via web-based methods, as requested. Training shall be initiated within 30 days of award and shall continue throughout the duration of the contract.

The Contractor shall provide course outlines to include a detailed training agenda (pre-approved by FDA) for the overview of the OTC data resource(s) and the hands-on computer-based training offered. Training manuals and course outlines shall be provided in hard-copy at the time of training.

G. Onsite Kick-Off and Annual Meeting

The Contractor shall participate in a kick-off meeting within two weeks of award and shall conduct an annual meeting on-site at the FDA campus in Silver Spring, MD once a year. The purpose of the annual meeting is to discuss scientific issues of interest to the Agency and relevant work that the Contractor has performed, as well as discussing FDA satisfaction with all deliverables.

H. Technical Support Requirements – Support Package – Technical Analytical and Clinical; Data and Software Upgrades and New Releases; Monthly Usage Reports

The Contractor shall provide a support package comprised of web-based written documentation that includes technical, analytical, and clinical support throughout the length of the contract.

The Contractor shall provide ongoing technical, analytical, and clinical support, by phone or by e-mail, to all certified users of the data during business hours (9:00 am to 5:00 pm, EST), throughout the length of the contract in accordance with the service levels established in the contract.

The support package shall include all upgrades, enhancements, and modifications to the software and data.

I. Monthly Reports

The Contractor shall provide a Monthly Report by the 30th of each month to the COR and shall include, but are not limited to:

1. Monthly Usage Report: to include the number of data queries per approved Certified User
2. Ad Hoc Dataset Requests: to include the number of technical support programming hours used

3. Clearance Requests: to include data submitted, project title, purpose (publication, presentation, research, or other), FDA requestor, and approval date
4. Third Party Agreement Requests: to include third party collaborator, FDA principal investigator, approval date, expiration date, and project title
5. Notifications of any circumstances resulting in loss of, or lack of data streams, or any data errors that would impact access to data from the data resource(s).

J. Disclosure Clearance Services

a. Disclosure Clearance Services

The Contractor shall provide disclosure clearance services for FDA to use *aggregated data* in scientific and technical articles, study results, presentations, and public health advisories for these purposes outside of the Agency including the general public. The Contractor shall accept and adhere to the FDA Data Disclosure Clearance Procedures and form.

The FDA will notify the Contractor for a period of one year after Option Period 2 for *aggregated data* release to entities outside of the Agency and accept the Contractor's requested revisions, but will not require formal approval for release.

b. Clearance for Third Party Collaborations

The Contractor shall provide Third Party Collaborations in support of collaborative research projects with third parties outside of FDA that are initiated by and for the benefit of FDA. These collaborations shall require FDA to have the ability to share project specific *aggregated* or *raw data* with third parties for collaborative research projects. For these collaborations that require sharing of *aggregated* or *raw* data, the Contractor shall accept and adhere to the Data Disclosure Clearance Procedures and form found. These Procedures include terms and conditions for third party collaborations.

K. Additional types of services and associated maintenance would include but are not limited to:

The type of additional services and associated maintenance would include:

1. Concomitant drug reports – reports on the concomitant use of an OTC product(s) or class of products with another product(s) or class of products used to treat an ailment.
2. Feasibility studies - studies that are conducted as initial pilot studies to determine if the scope of a study is practical, achievable and likely to involve a large population size to determine a significant association or non-significance association between exposure and outcome.
3. Customized analysis – analysis of data that endeavor to answer a specific question that require additional tools beyond the current interface tool that is provided by the database.

4. Risk management studies – studies that endeavored to ascertain if a specific risk management program is effective to ensure that the benefits of the drug outweigh the risks.
5. Training services – training staff for a specific service. For example, training medical records abstractors on the pertinent information required for abstracting medical record data based on medical record abstraction form.
6. Configuration of user interface tool – optimize configuration of user interface tool to provide FDA staff the ability to select drugs and perform data reports by active ingredient, generic and brand name, and any other data elements that may become available, and download in a timely manner and without or with minimal intervention by the Contractor.
7. Feasibility studies - studies that are conducted as initial pilot studies to determine if the scope of a study is practical, achievable and likely to involve a large population size to determine a significant association or non-significance association between exposure and outcome.
8. Customized analysis – analysis of data that endeavor to answer a specific question that require additional tools beyond the current interface tool that is provided by the database.
9. Risk management studies – studies that endeavored to ascertain if a specific risk management program is effective to ensure that the benefits of the drug outweigh the risks.
10. Training services – training staff for a specific service. For example, training medical records abstractors on the pertinent information required for abstracting medical record data based on medical record abstraction form.
11. Configuration of user interface tool – optimize configuration of user interface tool to provide FDA staff the ability to select drugs and perform data reports by active ingredient, generic and brand name, and any other data elements that may become available, and download in a timely manner and without or with minimal intervention by the Contractor. Ad Hoc Analyses – The Contractor shall provide additional hours of ad hoc data analyses or custom queries not available through the data tools and in increments TBD throughout the periods of performance. Concomitant drug reports – reports on the concomitant use of an OTC product(s) or class of products with another product(s) or class of products used to treat an ailment.

PLACE OF PERFORMANCE:

All work can be accomplished at the Contractor's facility and as needed at FDA’s Silver Spring, Maryland facility.

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Companies are encouraged to respond if they have the capability and capacity to provide the identified services.

Interested small business potential Offerors are encouraged to respond to this notice.

However, be advised that generic capability statements are not sufficient for effective evaluation of respondents' capacity and capability to perform the specific work as required.

Responses must directly demonstrate the company's capability, experience, and/or ability to marshal resources to effectively and efficiently perform each of the tasks described above at a sufficient level of detail to allow definitive numerical evaluation; and evidence that the contractor can satisfy the minimum requirements listed above while in compliance with FAR 52.219-14 ("Limitations on Subcontracting"). Failure to definitively address each of these factors will result in a finding that respondent lacks capability to perform the work.

Responses to this notice shall be limited to 15 pages, and must include:

1. Company name, mailing address, e-mail address, telephone and fax numbers, website address (if available), and the name, telephone number, and e-mail address of a point of contact having the authority and knowledge to clarify responses with Government representatives.

2. Name, title, telephone number, and e-mail addresses of individuals who can verify the demonstrated capabilities identified in the responses.

3. Business size for NAICS 518210 with size limitation standards of $32,500,000.00 and status, if qualified as an 8(a) firm (must be certified by the Small Business Administration (SBA), Small Disadvantaged Business (must be certified by SBA), Woman-Owned Small Business, HUBZone firm (must be certified by SBA), and/or Service-Disabled Veteran Owned Small Business (must be listed in the VetBiz Vendor Information Pages).

4. DUNS number, CAGE Code, Tax Identification Number (TIN), and company structure (Corporation, LLC, partnership, joint venture, etc). Companies also must be registered in the System for Award Management (SAM) at www.sam.gov to be considered as potential sources.

5. Identification of the firm's GSA Schedule contract(s) by Schedule number and contract number and SINs that are applicable to this potential requirement are also requested.

6. If the company has a Government approved accounting system, please identify the agency that approved the system.

Please submit copies of any documentation, such as letters or certificates to indicate the firm's status (see item #3 above).

Teaming arrangements are acceptable, and the information required above on the company responding to this announcement shall also be provided for each entity expected to be teammates of the respondent for performance of this work.

To the maximum extent possible, please submit non-proprietary information. Any proprietary information submitted should be identified as such and will be properly protected from disclosure.

Interested offerors should submit their capability statement not exceeding fifteen (15) pages in length, excluding standard brochures. **SUBMISSIONS ARE DUE no later than 10:00am, Eastern Time, April 28, 2017**. The capabilities response shall be e-mailed to: Monifa.Coleman@fda.hhs.gov.

All information received in response to this notice that is marked Proprietary will be handled accordingly. Responses to the notice will not be returned, nor will there be any ensuing discussions or debriefings of any responses. Information provided in response to this notice will be used to assess alternatives available for determining how to proceed in the acquisition process. This notice is part of Government Market Research, a continuous process for obtaining the latest information on the commercial status of the industry with respect to their current and near-term abilities. The information provided herein is subject to change and in no way binds the Government to solicit for or award a competitive contract.

The FDA will use the information submitted in response to this notice at its discretion and will not provide comments to any submission; however, the content of any responses to this notice may be reflected in subsequent solicitation. FDA reserves the right to contact any respondent to this notice for the sole purpose of enhancing FDA's understanding of the notice submission.

This announcement is Government market research, and may result in revisions in both its requirements and its acquisition strategy based on industry responses.

It is emphasized that this is a notice for planning and information purposes only and is not be construed as a commitment by the Government to enter into a contractual agreement, nor will the Government pay for information solicited